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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,904	02/16/2001	Tae-Yoon Lee	12777.8US01	3661

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EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,904

Applicant(s)

LEE ET AL.

Examiner

Juliet Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. An attempt has been made to identify as many of the problems in the claims as possible, but applicant is advised to review the claims as well.

(A) Claim 1 is indefinite because it does not clearly provide any method steps. The claims recites "A method for detecting Mycobacterium tuberculosis using polymerase chain reaction" but it is not clear if this language constitutes a method step or a preamble to the claim.

Amendment of the claim to clarify the method steps would obviate this rejection.

(B) Claim 1 further recites "polymerase chain reaction (PCR) with respect to all or some of the REP13E12 sequence" but it is not clear what it means to use PCR with respect to a sequence. Furthermore, the use of "REP13E12" to identify a sequence is indefinite because this is an arbitrary designation and it is not clear to what sequence this designation refers. It is recommended that the claim be amended to refer to the sequence by a proper sequence identifier.

(C) Claim 1 further recites "which exists only in Mycobacterium tuberculosis complex" but it is not clear if this language is meant to be a statement of an inherent property of the REP13E12

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sequence, or if this it is a further requirement that “the all or some of the REP13E12” sequence that is the target of the PCR be specific to the Mycobacterium tuberculosis complex.

(D) Claim 1 is further indefinite because it refers to a method for detecting Mycobacterium tuberculosis, yet it also refers to a sequence that is specific for the “Mycobacterium tuberculosis complex” and thus it is not clear if the method is directed to detect M. tuberculosis or the M. tuberculosis complex. Furthermore, it is not clear what the “Mycobacterium tuberculosis complex” or how it relates to Mycobacterium tuberculosis.

Claims 2-5 fail to remedy the problems cited in claim 1, and thus these claims are indefinite for the same reasons.

(E) Claim 2 is indefinite over the recitation “is consist of” because it is not clear what this transitional language means. The use of the language “consists of” would clarify the claim.

(F) Claim 2 is further indefinite over the recitation “corresponding to the sequence number 1” because it is not clear what it means for a sequence to “correspond” to a sequence.

Furthermore, it is not clear what “the sequence number 1” is referring to. If Applicant’s intention is to refer to SEQ ID NO: 1, proper sequence identifier language should be used.

(G) Claim 3 is indefinite over the language “devised on the basis of sequence number 2” because it is not clear what it means for a primer to be devised on the basis of another sequence.

Furthermore, it is not clear what “the sequence number 2” is referring to. If Applicant’s intention is to refer to SEQ ID NO: 2, proper sequence identifier language should be used.

(H) In claim 4, the phrase “the tuberculosis microbial cells separated from Korea or from the specimen of Korean tuberculosis patients” lacks proper antecedent basis in the claims. The

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claims do not previously refer to tuberculosis microbial cells separated from Korea or specimen of Korean tuberculosis patients.

(I) In claim 5, it is not clear what "the sequence numbers 3 and 4" is referring to. If Applicant's intention is to refer to SEQ ID NO: 3 and SEQ ID NO: 4, proper sequence identifier language should be used.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Tubercle and Lung Disease (1997) 78(1) 13-19).

Lee et al. teach a method for detecting Mycobacterium tuberculosis using PCR amplification to amplify all or a portion of a 435 bp repeat sequence (p. 17-18). The repeat sequence is identical to instant SEQ ID NO: 2 (Fig. 4), and the primers for amplification were obtained from within this repeat sequence (p. 17). This repeat sequence is a portion of instant SEQ ID NO: 1, thus it is inherently a portion of the REP13E12 repeated sequence. Lee et al. teach that the 435 bp repeat sequence is found in Korean M. tuberculosis strains (Fig. 3).

Thus, the teachings of Lee et al. meet the limitations of the instant claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. in view of Taylor (Methods in Molecular Biology (1997) 70:273-278).

Lee et al. teach a method for detecting *Mycobacterium tuberculosis* using PCR amplification to amplify all or a portion of a 435 bp repeat sequence (p. 17-18). The repeat sequence is identical to instant SEQ ID NO: 2 (Fig. 4), and the primers for amplification were obtained from within this repeat sequence (p. 17). This repeat sequence is a portion of instant SEQ ID NO: 1, thus it is inherently a portion of the REP13E12 repeated sequence. Lee et al. teach that the 435 bp repeat sequence is found in Korean *M. tuberculosis* strains (Fig. 3).

Instant SEQ ID NO: 3 consists of nucleotides 300-317 of the repeat sequence taught by Lee et al. in Figure 3, and instant SEQ ID NO: 4 consists of the complement of nucleotides 511-528 of the repeat sequence taught by Lee et al.

Lee et al. do not teach a method in which the primers used in amplification are instant SEQ ID NO: 3 and instant SEQ ID NO: 4.

However, methods for primer selection were routine in the art at the time the invention was made, and in fact a number of computer programs existed to assist scientists with primer selection. For example, Taylor discusses a software program called "GeneJockeyII" which generates primer pairs for a target sequence, allowing certain parameters to be selected by the practitioner. Taylor teaches that "GeneJockey can scan a given sequence to determine that areas of sequence are suitable to make primers for PCR (p. 274)."

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have selected primers from within the 435 base pair region taught by Lee et al. to use in a detection assay for the detection of *M. tuberculosis*. The ordinary practitioner would have been motivated by the teaching of Lee et al. that "several primers based on the repeat sequence" were used for PCR amplification and these assays resulted in specific and constant PCR amplification products when DNA from laboratory strains of clinical specimens was the target of interest (p. 17-18). The selection of any primers from within the 435 base pair region taught by Lee et al. is therefore obvious in view of the teachings of Lee et al. and the teachings of Taylor.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


JEFFREY FREDMAN
PRIMARY EXAMINER


Juliet C. Einsmann
Examiner
Art Unit 1634

April 15, 2002